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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,830	01/08/2002	Gary E. Borodic	33677-00000	2713

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,830	BORODIC ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *attached* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed March 1, 2004. Claims 1-15 have been cancelled. Claims 16-19 have been added. It should be noted that the species requirement between trigeminal neuralgia and facial pain has been withdrawn and both limitations will be examined as one species. See the Interview Summary dated May 25, 2004.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Objection Withdrawn

3. In view of Applicant's amendment the objection to the specification, page 2, paragraph 2 is withdrawn.

Rejections Maintained

4. The rejection under 35 U.S.C. 102 (e) is maintained for newly submitted claims 16-19 for the reasons set forth on pages 3-4, paragraph 3 of the previous Office Action.

The rejection was on the grounds that Aoki et al teach a method of treating pain caused by postherapeutic neuralgia (column 24, Example 3). Aoki et al teach that the patient was administered between 50 and 200 units of botulinum toxin A and within 1-7 days after neurotoxin administration patient's pain was substantially alleviated (column 24, Example 3). Claim limitation "wherein the neuralgia is associated with trauma" would be inherent in the teaching of the prior art because neuralgia is associated with trauma and pain. Aoki et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of

the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that nothing in Aoki et al anticipate or renders obvious the presently pending claims because there is no teaching or suggestion anywhere in Aoki et al of the claimed method for treating facial pain caused by trigeminal neuralgia. Applicant urges that post herpetic neuralgia is not trigeminal neuralgia and the two are recognized as being distinct by those skilled in the art. Applicant urges that pain caused by trigeminal neuralgia is an accepted distinct clinical syndrome with unique diagnostic criteria and etiology (causes). Applicant urges that one skilled in the art would not confuse facial pain caused by trigeminal neuralgia with other states associated with pain.

Applicant's arguments filed May 28, 2004 have been fully considered but they are not persuasive. Aoki et al teach that methods of treating pain by administering botulinum toxin (column 11, lines 66-67 and column 12). Aoki et al teach that the invention can be used to treat pain which results form a wide variety of neuropathic, inflammatory, cancerous and trauma conditions (column 16). Aoki et al teach that Neuropathic pain syndromes include allodynia, various neuralgia such as post herpetic neuralgia and trigeminal neuralgia, phantom pain and complex regional pain syndromes, such as reflex sympathetic dystrophy and causalgia (column 3, lines 29-35). One skilled in the art would recognize that Neuropathic pain syndromes includes trigeminal neuralgia. There is nothing on the record to show that the claimed method

differs from that of the prior art. Therefore, the teaching of Aoki et al anticipate the claimed method.

5. The rejection under 35 U.S.C. 102 (e) is maintained for newly submitted claims 16-19 for the reasons set forth on pages 4-5, paragraph 4 of the previous Office Action.

The rejection was on the grounds that Binder teaches a method of treating pain caused by trigeminal neuralgia by delivering an invertebrate presynaptic neurotoxin (botulinum toxin A) to a mammal (see the Abstract). Binder teaches that the botulinum toxin A is administered to the muscles of the face, cranium and neck (see the Abstract). Binder teaches that neurotoxin can be administered in a dose up to about 1000 units although individual dosages of about 15-30 units are preferred and dosages of 2.5 to 5 units will have therapeutic efficacy. Binder teaches that the neurotoxin will be administered as a composition at a dosage that is proportionally equivalent to about 2.5 cc/100 units (see columns 5-6). The claim limitation "wherein the neuralgia is associated with trauma" would be inherent in the teaching of the prior art because trigeminal neuralgia is associated with trauma and pain. Binder anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that nothing in Binder anticipates or renders obvious the presently pending claims because there is no teaching or suggestion anywhere in Binder of the claimed method for treating facial pain caused trigeminal neuralgia. Applicant urges that post herpetic neuralgia is not trigeminal neuralgia and the two are recognized as being distinct by those skilled in the art. Applicant urges that pain caused by trigeminal neuralgia is an accepted distinct clinical syndrome with unique diagnostic criteria and etiology (causes). Applicant urges that one skilled in the art would not

confuse facial pain caused by trigeminal neuralgia with other states associated with pain. Applicant urges that health care professional recognize that there are different diagnostic criteria in regard to trigeminal neuralgia, migraine and tension headaches.

Applicant's arguments filed May 28, 2004 have been fully considered but they are not persuasive. Binder teaches a method of alleviating pain from local areas such as face by the administration of botulinum toxin (column4, lines 5-37). Binder teaches that for example, as shown in the data presented in the Examples, the method of the invention was effective in reducing headache pain even in persons who only received an extramuscular injection of presynaptic neurotoxin. Moreover, reduction of headache pain was unexpectedly observed even in patients whose pain was causally related to vascular or neurological components; e.g., classical migraine, trigeminal neuralgia and trauma headache. However, those of ordinary skill in the art will recognize that additional therapeutic benefits may be achieved through introduction of the presynaptic neurotoxins of the invention into musculature (column 6, lines 58-67 and column 7, lines 1-3). It should be noted that Table 1(b) discloses that trigeminal neuralgia is associated with facial nerves (column 2). One skilled in the art would recognize that botulinum toxin can be used to treat headaches as well as trigeminal neuralgia. To address Applicant's comments regarding the diagnostic distinction between trigeminal neuralgia, migraine and tension headaches, the art recognizes that theses disorders are distinct one from the other however, Binder teaches that botulinum toxin can be used to treat any of these disorders column 6, lines 58-67 and column 7, lines 1-3). There is nothing

on the record to show that the claimed method differs from that of the prior art.

Therefore, the teaching of Binder anticipates the claimed method.

Status of Claims

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
August 22, 2004

L. R. F. Smith
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